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(54) Title: PROCESS FOR THE PREPARATION OF ROBUST FORMULATIONS OF VALACYCLOVIR HYDROCHLORIDE **TABLETS** 

(57) Abstract: The invention relates to robust formulations of valacyclovir hydrochloride tablets. A robust tablet includes a hydrated form of valacyclovir hydrochloride having a water of hydration content of more than approximately 3% w/w and a particle size of less than approximately 355 µm.

A. CLASSIFICATION OF SUBJECT MATTER IPC 7 A61K9/20 A61K31/522

According to International Patent Classification (IPC) or to both national classification and IPC

### B. FIELDS SEARCHED

 $\begin{array}{ll} \mbox{Minimum documentation searched (classification system followed by classification symbols)} \\ \mbox{IPC 7} & \mbox{A61K} \end{array}$ 

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

WPI Data, PAJ, CHEM ABS Data

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 97 25989 A (GLAXO) 24 July 1997 (1997-07-24) claims examples	1-43
X	WO 96 22291 A (WELLCOME FOUNDATION) 25 July 1996 (1996-07-25) cited in the application claims examples 5,6	1-43
X	WO 96 22082 A (WELLCOME FOUNDATION) 25 July 1996 (1996-07-25) cited in the application claims examples	1-43

Further documents are listed in the continuation of box C.	X Patent family members are listed in annex.
Special categories of cited documents:  'A' document defining the general state of the art which is not considered to be of particular relevance  'E' earlier document but published on or after the International filling date  'L' document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another clation or other special reason (as specified)  'O' document referring to an oral disclosure, use, exhibition or other means  'P' document published prior to the international filing date but later than the priority date claimed	<ul> <li>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</li> <li>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone</li> <li>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</li> <li>"&amp;" document member of the same patent family</li> </ul>
Date of the actual completion of the international search	Date of mailing of the International search report
10 February 2004	24/02/2004
Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Scarponi, U



Interna Application No
PCT/IB 03/02456

	tion) DOCUMENTS CONSIDERED TO BE RELEVANT	
Category °	Citation of document, with Indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 96 32097 A (PHARMA PASS) 17 October 1996 (1996-10-17) claims 1-5,12,19-26 examples 1,2,11	1-43
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# INTERNATIONAL SEARCH REPORT

International application No. PCT/IB 03/02456

Box I	Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)
This Inte	ernational Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:
1. χ	Claims Nos.: because they relate to subject matter not required to be searched by this Authority, namely:
	Although claims 22-27 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.
2.	Claims Nos.: because they relate to parts of the international Application that do not comply with the prescribed requirements to such an extent that no meaningful international Search can be carried out, specifically:
	•
з. 🗌	Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).
Box II	Observations where unity of invention is lacking (Continuation of Item 2 of first sheet)
This into	ernational Searching Authority found multiple inventions in this international application, as follows:
JIII em .	Continued to the state of the s
1.	As all required additional search fees were timely paid by the applicant, this international Search Report covers all searchable claims.
2.	As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3.	As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4.	No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the Invention first mentioned in the claims; it is covered by claims Nos.:
Remark	k on Protest The additional search fees were accompanied by the applicant's protest.
	No protest accompanied the payment of additional search fees.

# INTERNATIONAL SEARCH REPORT Information on patent family members

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